DOM06 – Procedures for Internal/External Audits

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1. Background

1.1. The Department of Forensic Sciences (DFS) will periodically conduct internal audits and management reviews in accordance with a predetermined schedule. DFS will also submit to audits, assessments, and/or inspections administered by external organizations to assure ongoing compliance with accreditation requirements in accordance within an appropriate/agreed upon timescale.

1.2. Periodic audits and reviews are used to evaluate and continually improve the effectiveness of the management system through the use of audit results, analysis of data, quality corrective and preventive actions, and management review of the DFS division entities, specifically Crime Scene Sciences (CSS), the Forensic Science Laboratory (FSL), and the Public Health Laboratory (PHL). These procedures conform to the requirements of the Agency, government regulations, accreditation standards, and the applicable supplemental standards.

2. Definitions

2.1. For the purposes of this document, the following terms shall have the designated meanings:

CSS: Crime Scene Sciences

DFS: Department of Forensic Sciences

DOM: Departmental Operations Manual

FBI: Federal Bureau of Investigation

FBU: Forensic Biology Unit

FSL: Forensic Sciences Laboratory

PHL: Public Health Laboratory

Q-CAR: Quality Corrective Action Reports

Q-PAR: Quality Preventive Action Reports

SOP: Standard Operating Procedures

3. Scope

3.1. These procedures are applicable to the internal audit program performed in the DFS. They involve all elements of the management system and testing activities to verify that operations continue to comply with DFS requirements and applicable standards, to ensure continued suitability and effectiveness, and to introduce necessary changes to improvements.

3.2. The internal audit program will address all elements of the management system including testing activities. This will be achieved through annual assessments of all elements of the management system, operations affecting quality, quality system requirements, internal quality policies and procedures, standard operating procedures, records, equipment, and facilities by trained/qualified personnel who are, wherever resources permit, independent of the activity to be audited.

3.2.1. Findings from internal audits and actions that arise from them will be recorded and carried out within an appropriate/agreed timescale.

3.3. The external audit program will address those criteria specified by the organization conducting the audit, assessment or inspection. Typically, a representative sampling of elements of the management system, including testing activities, are reviewed during external audits. This is achieved through assessments of elements of the management system, operations affecting quality, quality system requirements, internal quality policies and procedures, standard operations procedures, records, equipment, and facilities by trained/qualified personnel who are independent of the DFS.

4. Responsibilities

4.1. The **Quality Assurance Specialist** will:

4.1.1. Prepare and organize an audit schedule.

4.1.2. Read the standards and understand the requirements that are being covered in the audit.

4.1.3. Ensure trained/qualified auditors are selected, as necessary.

4.1.4. Coordinate audit activities of the assigned auditors.

4.1.5. Collect audit data through means such as reviewing documentation, interviewing personnel, observing operations and observing conditions and facilities.

4.1.6. Receive team responses and ensure an audit report is prepared for each audit conducted.

4.1.7. Implement corrective action procedures in accordance with *DOM07 – Practices for Quality Corrective Actions* and/or preventive action procedures in accordance with *DOM08 – Procedures for Preventive Actions*.

4.1.8. Write the Summary and Findings audit report.

4.1.9. Provide a completed checklist and supporting materials.

4.1.10. Ensure audit activities are documented, which may include the Internal Audit Lead Auditor Checklist, the Internal Audit Observation Form, and a Summary and Findings Report. Documentation will be provided to the Deputy Director.

4.1.11. Close out the audit, when appropriate.

4.2. The **Deputy Director** or designee will:

4.2.1. Ensure the predetermined schedule of internal audits and management reviews for the Agency.

4.2.2. Select the Quality Assurance Specialist to lead the audit and provide a list of trained/qualified personnel who are eligible to serve on the audit team.

4.2.3. Monitor the progress of all audits and reviews to ensure compliance with DFS requirements and applicable regulations and standards.

4.2.4. Approve all internal audit reports before they are issued.

4.2.5. Receive responses to all external audit reports.

4.2.6. Implement quality corrective action procedures when nonconformity is identified through an audit.

4.2.7. Submit an Annual Accreditation Audit Report to applicable International Standards accreditation vendor and/or other certifying body within thirty (30) calendar days of the scheduled surveillance assessment or certification anniversary date.

5. Procedures

5.1. External Audits or Inspections

5.1.1. Every year, an external audit of the FSL Forensic Biology Unit (FBU) must be conducted by qualified auditors. External audits of the appropriate Division's Quality system shall follow the schedule determined by the contracted ISO/IEC 17025 accreditation vendor and/or certifying body.

5.1.2. For the FSL, the auditor(s) will assess the quality system requirements against the ISO/IEC 17025:2017 standards and supplemental guidelines.

5.1.2.1. For the FSL FBU, the auditor(s) will assess the quality system requirements and the DNA testing process utilizing the FBI Quality Assurance Standards (QAS) Audit for Forensic DNA Testing Laboratories document and the ISO/IEC 17025:2017 standards and supplemental guidelines to ensure compliance.

5.1.2.2. Whenever an external DNA QAS audit is conducted, the FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories document along with the laboratory responses must be submitted to the FBI within thirty (30) days of receipt of the completed audit document from the external audit team. Review of this document under the direction and documented approval of the FBU Manager and FBU Technical Leader prior to submission to the FBI is required.

5.1.3. Quality corrective and preventive actions regarding findings or nonconformance will be taken in accordance with the appropriate procedure and, when required, a report/nonconformance response will be sent to the external auditor or to the agency within the specified time.

5.1.4. If appropriate quality corrective and preventive actions could not be completed within the specified time, the external auditor or agency will be notified in writing and an extension date will be requested to complete the corrective actions.

5.2. Internal Audits

5.2.1. Internal Audits of the entire laboratory shall be conducted at least once per calendar year. These audits may include, but are not limited to security, unit quality manuals and standard operating procedures (SOPs), evidence management, training records, instrument calibration

and maintenance, case files, court testimony monitoring and proficiency testing. Additionally, periodic laboratory inspections of selected areas may be conducted at the discretion of management.

5.2.2. Scheduling the Audits

5.2.2.1. Throughout the year, the Deputy Director will ensure the appropriate Division Director and Quality personnel are notified to schedule audits in accordance with a predetermined schedule and contact appropriate management to determine mutually agreeable dates for the audits.

5.2.3. Preparation

5.2.3.1. The Deputy Director or Quality Assurance Specialist may serve as the Lead Auditor or may select an auditor when necessary based on the magnitude of the audit. The Lead Auditor may select others, as needed, with appropriate qualifications to assist in performing the audit. Additionally, the Lead Auditor will furnish any assistants with the appropriate training, instructions, guidance, and materials so that they can prepare and conduct the audit.

5.2.3.2. The Lead Auditor will ensure a checklist is prepared to prompt the auditor(s) to observe operations and review necessary documentation.

5.2.3.3. The auditors should be familiar with the audit checklist as well as any additional documents containing requirements for which conformance is being audited.

5.2.4. Conducting the Audit

5.2.4.1. The auditor(s) will, as necessary, review documentation, interview personnel, and observe operations, conditions, and facilities to collect data on conformance with requirements and effectiveness of quality control measures. The audit checklist, and additional sheets of paper, as necessary, will be used to record the audit data.

5.2.4.2. If necessary, the audit team will meet to review the progress of the audit and any issues that need to be discussed.

5.2.4.3. If necessary, the Lead Auditor will conduct a post-audit conference to inform the Unit Manager of the audit data. The Unit Manager should inform the Lead Auditor of any disagreements that s/he has with the preliminary data. These issues will be considered by the

Lead Auditor and, if possible, resolved before the audit report is written.

5.2.5. Internal Audit Report

5.2.5.1. The Lead Auditor will write an audit report for every audit conducted to formally notify the unit and management of the audit results. An audit report will include any nonconformities. If the unit satisfactorily corrects a nonconformity before the audit report is issued, that nonconformity will not be included as a finding in the audit report or will be denoted as corrected prior to the conclusion of the audit within the audit report [*DOM07 – Practices for Quality Corrective Action*].

5.2.5.2. The audit report is approved by the Deputy Director and issued by the Lead Auditor. The approval and issuance are documented on the audit report by their respective signatures and dates.

5.2.5.3. If an audit report contains nonconformities, Quality Corrective Action Report(s) may be created for each nonconformity. If the audit report identifies needed improvements and/or potential sources of nonconformity, a Quality Preventive Action Request may be created.

5.2.5.4. Copies of the audit report will be provided to the Laboratory Director and Deputy Director.

5.2.5.4.1. Following review under the direction and documented approval of the FBU Manager and FBU Technical Leader, the FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories document with responses, will be maintained in the FSL/FBU.

5.2.6. Responding to the Audit Report

5.2.6.1. The Division Manager, Unit Manager, or designee will acknowledge receipt of the audit report.

5.2.6.2. If the laboratory initiates a Quality Corrective or Preventive Action Report as a result of the audit findings, it must be completed and returned to management for approval. For instructions on completing these forms and remediation procedures see the appropriate DOM07 or DOM08 sections.

6. Documentation

6.1. The following records will be generated as a result of these procedures. Originals will be retained by each Division, with electronic copies provided to the Deputy Director.

6.1.1. Annual audit schedule will be retained for at least one (1) accreditation cycle or five (5) years, whichever is longer.

6.1.2. Completed audit checklists will be retained for at least one (1) accreditation cycle or five (5) years, whichever is longer.

6.1.3. Audit reports and any associated responses will be retained permanently.

6.1.4. When necessary, Quality Corrective Action Reports will be retained according to the requirements in the [*DOM07 – Practices for Quality Corrective Action*].

6.1.5. When issued, Quality Preventive Action Requests will be retained according to the requirements in the [*DOM08 – Procedures for Quality Preventive Action*].

6.1.6. Audit closure memos will be retained for at least one (1) accreditation cycle or five (5) years, whichever is longer.

6.1.7. Annual final audit reports will be retained permanently.

7. References

7.1. ISO/IEC 17025: – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, (current revision)

7.2. ANAB Supplemental Requirements for Forensic Testing, ANSI-ASQ National Accreditation Board, Milwaukee, WI, (current revision).

7.3. Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision).

7.4. Division-specific Quality Assurance Manuals, (current revisions).

7.5. DOM07 – Practices for Quality Corrective Action Reports, (current revision).

7.6. DOM08 – Procedures for Quality Preventive Action Reports, (current revision).